



Senate

General Assembly

January Session, 2001

File No. 150

Senate Bill No. 46

Senate, April 9, 2001

The Committee on Public Health reported through SEN. HARP of the 10th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT REQUIRING HEALTH INSURANCE POLICIES TO COVER MEDICALLY NECESSARY INFANT NUTRITIONAL FORMULA.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 38a-492c of the general statutes is repealed and the
2 following is substituted in lieu thereof:

3 (a) For purposes of this section:

4 (1) "Inherited metabolic disease" means a disease for which
5 newborn screening is required under section 19a-55.

6 (2) "Low protein modified food product" means a product
7 formulated to have less than one gram of protein per serving and
8 intended for the dietary treatment of an inherited metabolic disease
9 under the direction of a physician.

10 (3) "Amino acid modified preparation" means a product intended
11 for the dietary treatment of an inherited metabolic disease under the

12 direction of a physician.

13 (4) "Specialized formula" means a nutritional formula for infants
14 that is exempt from the general requirements for nutritional labeling
15 under the statutory and regulatory guidelines of the federal Food and
16 Drug Administration and is intended for use solely under medical
17 supervision in the dietary management of specific diseases.

18 (b) Each individual health insurance policy providing coverage of
19 the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of
20 section 38a-469 delivered, issued for delivery or renewed in this state
21 on or after October 1, 1997, shall provide coverage for amino acid
22 modified preparations and low protein modified food products for the
23 treatment of inherited metabolic diseases if the amino acid modified
24 preparations or low protein modified food products are prescribed for
25 the therapeutic treatment of inherited metabolic diseases and are
26 administered under the direction of a physician.

27 (c) Each individual health insurance policy providing coverage of
28 the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of
29 section 38a-469 delivered, issued for delivery or renewed in this state
30 on or after October 1, 2001, shall provide coverage for specialized
31 formulas when such specialized formulas are medically necessary for
32 the treatment of a disease or condition and are administered under the
33 direction of a physician.

34 Sec. 2. Section 38a-518c of the general statutes is repealed and the
35 following is substituted in lieu thereof:

36 (a) For purposes of this section:

37 (1) "Inherited metabolic disease" means a disease for which
38 newborn screening is required under section 19a-55.

39 (2) "Low protein modified food product" means a product
40 formulated to have less than one gram of protein per serving and

41 intended for the dietary treatment of an inherited metabolic disease
42 under the direction of a physician.

43 (3) "Amino acid modified preparation" means a product intended
44 for the dietary treatment of an inherited metabolic disease under the
45 direction of a physician.

46 (4) "Specialized formula" means a nutritional formula for infants
47 that is exempt from the general requirements for nutritional labeling
48 under the statutory and regulatory guidelines of the federal Food and
49 Drug Administration and is intended for use solely under medical
50 supervision in the dietary management of specific diseases.

51 (b) Each group health insurance policy providing coverage of the
52 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section
53 38a-469 delivered, issued for delivery or renewed in this state on or
54 after October 1, 1997, shall provide coverage for amino acid modified
55 preparations and low protein modified food products for the treatment
56 of inherited metabolic diseases if the amino acid modified preparations
57 or low protein modified food products are prescribed for the
58 therapeutic treatment of inherited metabolic diseases and are
59 administered under the direction of a physician.

60 (c) Each group health insurance policy providing coverage of the
61 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section
62 38a-469 delivered, issued for delivery or renewed in this state on or
63 after October 1, 2001, shall provide coverage for specialized formulas
64 when such specialized formulas are medically necessary for the
65 treatment of a disease or condition and are administered under the
66 direction of a physician.

PH *Joint Favorable*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact: Future Cost

Affected Agencies: Office of the State Comptroller

Municipal Impact: Potential Cost

Explanation**State Impact:**

The bill requires certain group and individual health insurance policies to cover “specialized formula” for infants when its use is medically necessary to treat a disease or condition and it is administered under a physician’s direction.

The coverage of medically necessary infant formula is not provided under the current state employees plans. The Office of the Comptroller has indicated that there would be a minimal fiscal impact associated with this mandated coverage that would be incurred in FY 04 when the state is expected to enter into new health insurance contracts.

Municipal Impact:

To the extent that medically necessary infant formula is not covered by a municipality’s employee health insurance policy, there may be increased municipal costs to provide it. The bill’s impact will vary by

municipality depending on the current coverage and cannot be determined at this time.

OLR Bill Analysis

SB 46

AN ACT REQUIRING HEALTH INSURANCE POLICIES TO COVER MEDICALLY NECESSARY INFANT NUTRITIONAL FORMULA.**SUMMARY:**

This bill requires certain group and individual health insurance policies to cover “specialized formula” for infants when its use is medically necessary to treat a disease or condition and it is administered under a physician’s direction. It defines a specialized formula as a nutritional formula that is (1) exempt from the federal Food and Drug Administration’s (FDA) general requirements for nutritional labeling and (2) intended for use solely under medical supervision in the dietary management of specific diseases.

The bill applies to group and individual hospital and medical service plans offered by HMOs and insurance policies that offer the following types of coverage: (1) basic hospital, (2) basic medical-surgical, (3) major medical, (4) accident only, and (5) hospital or medical expense. It affects policies and plans issued or renewed after September 30, 2001.

EFFECTIVE DATE: October 1, 2001

BACKGROUND***FDA Regulations***

FDA regulations require nutritional labeling for all products intended for human consumption, with certain exceptions including infant formula, which is regulated separately (21 CFR 101.9 (a) and (j)(7)). The infant formula labeling rules further exempt certain types of formula that are represented and labeled for use by infants who have inborn metabolic disorders, low birth weights, or unusual medical or dietary problems. FDA distinguishes between two types of exempt

formulas—those generally available at retail and those that are not. The former are typically labeled for use to provide dietary management for diseases or conditions that are not clinically serious or life-threatening, although they can also be labeled for use for serious or life-threatening conditions. The latter are typically prescribed by a physician and must be requested from a pharmacist. They are labeled for dietary management of specific diseases or conditions that are clinically serious or life-threatening, and are generally required for prolonged periods (21 CFR 107.50).

Related Bill

The Insurance and Real Estate Committee favorably reported SB 424, An Act Concerning Health Insurance Coverage for Medically Necessary Infant Formula, to the floor on March 27. It is substantively the same as this bill.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Report
Yea 24 Nay 0